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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,257	02/08/2002	Boyong Li	141-242A	9034

47888 7590 12/04/2008
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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
12/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,257	LI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/29/08 has been entered.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 36-43 and 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Percel et al (US 2001/0046964 hereafter '964). The claims are drawn to a once-a-day bupropion formulation comprising an immediate release portion, an enteric release portion and a sustained release portion.

The '964 patent discloses a once-a-day formulation comprising various possible active agents including bupropion [0020]. The formulation comprises an immediate release core comprising the active agent, an enteric release component comprising a pH dependent polymer

coating surrounding the core pellet such as a methacrylic acid copolymer, and a sustained release component comprising a water insoluble polymer surrounding the enteric coated core such as ethylcellulose [Table 1]. The sustained release component further comprises a methacrylic acid copolymer [Table]. The dosage form comprises approximately 197.5 grams of the active agent [Table 1].

Regarding the in vivo plasma profile it is the position of the Examiner that such limitations would be inherent to any formulation meeting the structural limitations of the instant invention. Since plasma profiles are determined by the physical characteristics of a dosage form such as the polymer types, concentration and configuration, along with the types and concentration of the particular drugs, it is the position of the Examiner that any dosage from meeting the physical limitations of the instant invention would also meet any in vivo plasma profiles claimed. The '964 patent teaches an extruded composition comprising a core which further comprises a carrier and at least one aminoketone antidepressant. The '964 patent further teaches the inclusion of each polymer claimed. Therefore it is the position of the Examiner that since each physical characteristic of the instantly claimed dosage from is met by the teachings of the '964 patent, the in vivo plasma profile is also met inherently.

Further the plasma profile would have been obvious to one of ordinary skill in the art. Since the general conditions of the claims have been met by the '964 patent, specifically the same polymers and drugs are used in an identical formulation, any manipulation of these parameters would be obvious to one of ordinary skill in the art. Likewise results falling from this manipulation would be obvious to one of ordinary skill in the art. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Further the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With these things in mind it would have been obvious to one of ordinary skill in the art to optimize the parameters of the '964 patent in order to achieve the desired plasma release rate since the patent discloses the same structural elements. It would have been obvious to optimize the component concentrations with an expected result of a controlled release formulation with improved release.

Claims 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Percel et al (US 2001/0046964 hereafter '964) in view of Chen et al (USPN 6,270,805 hereafter '805).

As discussed above the '964 patent discloses a once-a-day bupropion formulation comprising an immediate release portion, an enteric component and a sustained release portion. The reference is silent to the specific embodiments of capsules or tablets, although coated pellets

identical to the instant claims are disclosed. Combining coated pellets into a hard or soft capsule or compressing them into a tablet is well known in the art as seen in the '805 patent.

The '805 patent discloses a multi-unit controlled release dosage form comprising coated pellets comprising bupropion (abstract, col. 3, lin. 5-10). The pellets cores are coated with enteric polymers such as methacrylic acid copolymers and water-insoluble polymers such as ethylcellulose (col. 3, lin. 15-45). The coated pellets are placed into soft or hard gelatin capsules or formed into tablets (col. 5, lin. 10-15). It would have been obvious to combine the coated pellets of the '964 patent into hard or soft capsules as described in the '805 patent since both patent disclose similarly coated pellet formulations.

It would have been obvious to combine the teachings and suggestions of the prior art in order to provide an easier method of oral delivery for the controlled release pellets of the '964 patent. It would have been obvious to combine the pellets of the '964 into the capsules or tablets of the '805 patent. One of ordinary skill in the art would have been obvious to combine the prior with an expected result of a stable oral formulation with an ease of delivery.

Response to Arguments

Applicant's arguments filed 8/29/08 have been fully considered but they are not persuasive. Applicant argues that:

> The '964 patent does not discloses a coated pellet comprising both a water-insoluble polymer and an enteric polymer.

As discussed above it remains the position of the '964 patent discloses a coated pellet formulation comprising both methacrylic acid copolymer and ethylcellulose, a combination of

both an enteric polymer and a water insoluble polymer. The '964 patent discloses a once-a-day bupropion comprising an immediate release portion comprising bupropion, an enteric release component comprising bupropion and methacrylic acid, and a sustained release component comprising bupropion and a water insoluble polymer identical t that of the instant claims. The formulation is identical to that of the instant claims and as such would inherently have the same mean Cmax, AUC and Tmax values. For these reasons the claims remain rejected.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618